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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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08/900,559    07/25/97    CHENG    S    226/242

022249  
LYON AND LYON LLP  
SUITE 4700  
633 WEST FIFTH STREET  
LOS ANGELES CA 90071-2066

HM12/0712

EXAMINER

HINES, J

ART UNIT

PAPER NUMBER

1641

14

DATE MAILED:

07/12/99

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

# Office Action Summary

Application No.  
**08/900,559**

Applicant(s)  
**Cheng et al.**

Examiner  
**Ja-Na Hines**

Group Art Unit  
**1641**



☒ Responsive to communication(s) filed on May 10, 1999

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

## Disposition of Claims

☒ Claim(s) 10-20 is/are pending in the application.

Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

☐ Claim(s) \_\_\_\_\_ is/are allowed.

☒ Claim(s) 10-20 is/are rejected.

☐ Claim(s) \_\_\_\_\_ is/are objected to.

☐ Claims \_\_\_\_\_ are subject to restriction or election requirement.

## Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been  
☐ received.

☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

☒ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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## DETAILED ACTION

### *Claim Rejections - 35 USC § 102*

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 10-11, 13-15 and 17-20 is rejected under 35 U.S.C. 102(b) as being anticipated by Imrich et al. Imrich et al., teaches a lateral flow medical diagnostic assay device with sample extraction means. The device comprises an extraction chamber, a labeling zone, a matrix which defines a flow path, a sample receiving zone and a capture zone (col. 3 lines 48-53). The extraction chamber allows for pretreatment of a sample generally presented on a swab (col. 3 lines 60-66). The extraction solution may added to the chamber, and may be treated with an acidic extraction solution such as nitrous acid to expose Group A streptococcus specific antigen (col. 4 lines 15-20). The extraction solution may contain nitrous acid which is relatively unstable, as a result, to generate nitrous acid, sodium nitrite and acetic acid must be mixed immediately before initiation of the antigen extraction process (col. 8 lines 50-63). In one example an equal volume of 1M sodium nitrite and 1M acetic acid was applied as the extraction solution and the swab was fully rotated in the extraction chamber (col. 11 lines 49-53). This assay device is capable of non-bibulous flow using a matrix material such as a manufactured

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membrane with open pore structure (col. 4 lines 25-63). The matrix comprises at least two zones, a sample receiving zone and a capture zone (col. 4 lines 64-66). The sample receiving zone may contain a neutralizing agent which will neutralize the extraction solution and may be placed on the surface of the sample receiving zone (col. 5 lines 1-7). The labeling zone is present on the matrix and is between the sample receiving zone and the capture zone (col. 5 lines 9-13). The labeling means will generally be a labeled immunoglobulin, such as an antibody specific for the target analyte (col. 5 lines 15-26). As the treated sample flows through the labeling zone, the target analyte in the sample binds the labeled antibody thereby indirectly labeling the target antibody and then the sample continues its flow through into the capture zone where labeled target analyte is immobilized in the capture zone labeled target analyte will bind the immobilized immunoglobulins thereby retaining label in the capture zone (col. 5 lines 45-50). The presence of analyte will be determined by visual identification of label retention in the capture zone (col. 5 lines 50-52). The control procedure line is located downstream of the capture zone and retention of the label by the control procedural line indicates that the sample has flowed through the capture zone and contacted the immobilized target specific binding substance (col. 5 lines 58-60). The assay may include a pH indicating agent where a neutralized extraction solution will convert the end of assay indicator from bright yellow to blue (col. 6 lines 26-43). The component may contain two plastic removable pieces, the top piece contains the sample processing feature, the bottom piece is used for strip placement (col. 7 lines 37-41). Filters may be placed in the extraction chamber to remove particulate matter (col. 7 lines 42-48). The

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examples found at col. 10 line 10, explicitly describes detection of Group A streptococcus by means of a lateral flow assay using a nitrous acid extraction solution made in equal volumes of 1M sodium nitrate and 1M acetic acid.

Therefore, Imrich et al., teaches the invention as claimed.

***Claim Rejections - 35 USC § 103***

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 12 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Imrich et al., in view of Bogart et al. Imrich et al., has been previously discussed, however Imrich et al., does not teach the vigorous mixing or an extraction solution where the addition of the extraction materials are of similar concentrations. Bogart et al., teaches extraction methods for Group A streptococcus (col. 6 lines 10-18). Bogart et al., teaches a standard nitrous acid extraction method as being a mixture of 0.25M acetic acid and 2.3M sodium nitrate to generate nitrous acid. Antigen is extracted from the organism for 5 minutes, although the range is instantaneous to 30 minutes. Further, the solution is neutralized using a buffer. (col. 10-11).

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Therefore, it would have been obvious to one of ordinary skill in the art to optimize the experimental parameters and reagents of the method of Imrich et al., by selecting such conventional components for generating nitrous acid and times of extraction as taught by Bogart et al., where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill.

5. The Declaration of Richard H. Schwartz under 37 CFR 1.132 filed May 10, 1999 is insufficient to overcome the rejection of claims 10-20 based upon Imrich et al., alone or in combination with Bogart et al., because it refers to OSOM<sup>TM</sup> system and not to the individual claims of the instant application. The declaration makes references to the OSOM<sup>TM</sup>'s type of housing and its overall sensitivity, however those features are not relevant to the claims of the instant application. Thus, there is no showing that the objective evidence of nonobviousness is commensurate in scope with the claims. See MPEP § 716. Therefore, the Schwartz Declaration is not persuasive.

#### ***Prior Art***

6. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Chan et al., teaches a dipstick immunoassay for determining grain protein wherein dip-stick is coated with monoclonal antibodies. Eisenger et al., teaches a lateral flow assay for Group A streptococcus. Fischetti et al., teaches detection of Group A streptococcal antigens

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using an extraction step. Frisen et al., teaches conventional immunochromatographic test devices. Huang et al., teaches an immunochromatographic test device. Maggio teaches an immunoassay and incubation device. Murray et al., teaches coloring assay reagents which results in a color change to indicate which steps are completed.

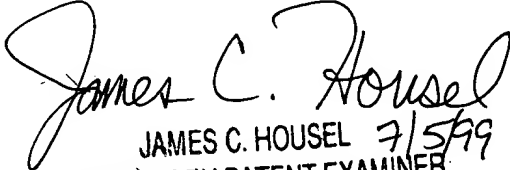
7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ja-Na Hines whose telephone number is (703) 305-0487. The examiner can normally be reached on Monday through Thursday from 6:30am to 4:00pm. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached on (703) 308-4027. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Ja-Na Hines

June 28, 1999

  
JAMES C. HOUSEL 7/5/99  
SUPERVISORY PATENT EXAMINER